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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,093	07/25/2003	William R. Ewing	USA2575USCNT1	4277
5487	7590	09/17/2008	EXAMINER	
ANDREA Q. RYAN			SACKEY, EBENEZER O	
SANOFI-AVENTIS U.S. LLC			ART UNIT	PAPER NUMBER
1041 ROUTE 202-206			1624	
MAIL CODE: D303A				
BRIDGEWATER, NJ 08807				
NOTIFICATION DATE		DELIVERY MODE		
09/17/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com  
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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/628,093	EWING ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	EBENEZER SACKY	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 April 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) 5,6,10,11,13,14,16-18,29,31,33,34,36-43 and 45-48 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4,7-9,12,15,19-28,30,32,35 and 44 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/01/03.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_ .

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

**Status of the Claims**

Claims 1-48 are pending.

***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

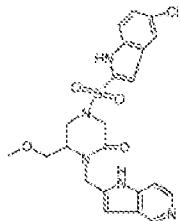
***Information Disclosure Statement***

Receipt of the Informational Disclosure Statement filed on 10/01/03 is acknowledged and has been entered into the file. A signed copy of the 1449 is attached herewith.

***Response to Restriction***

Applicant's election of Group I, claims 1-44 and species of Example 1116 i.e., 4-(5-chloro-1H-indole-2-sulfonyl)-6-methoxymethyl-1-(1H-pyrrolo[3,2-c]pyridine-2-

ylmethyl)-piperazin-2-one



in the reply filed on 04/14/08 is

acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The generic description encompassing the elected species is follows:

A is N,

n is 1,

m is 1,

R<sub>2</sub> is -CH<sub>2</sub>-O-CH<sub>2</sub>,

R<sub>1</sub>, R<sub>1a</sub>, R<sub>4</sub>, R<sub>4a</sub>, R<sub>2a</sub>, are as defined,

R<sub>3</sub> and R<sub>3a</sub> taken together form O,

G<sub>1</sub> is L<sub>1</sub>.Cy<sub>1</sub> where L<sub>1</sub> is SO<sub>2</sub> and Cy<sub>1</sub> is substituted or optionally substituted heteroaryl or substituted or optionally substituted fused arylheteroaryl,

G<sub>2</sub> is L<sub>2</sub>.Cy<sub>2</sub> where L<sub>2</sub> is CH<sub>2</sub> and Cy<sub>2</sub> is substituted or optionally substituted heteroaryl or substituted or optionally substituted fused arylheteroaryl.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

R<sub>2</sub> has been defined as alkoxyalkyl, carboxyalkyl, hydroxyalkyl or heterocyclalkyloxycarbonyl, there is lack of antecedent base for these limitations since claim 19, from which 30 depends has not define R<sub>2</sub> as such.

***Claim Rejections - 35 U.S.C. § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

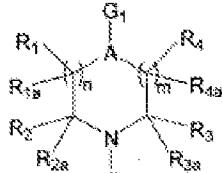
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-4, 7-9, 12, 15, 19-28, 30, 32, 35 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su et al., (U.S. Patent number 6,369,063).

Applicants claim compounds and compositions containing compounds of



structural formula (I) The definition of the substituents are as stated in claim 1 and subsequent claims.

#### **Determination of the scope and content of the prior art (MPEP §2141.01)**

Su et al., teach compounds and compositions containing compounds of formula (I), similar to the current invention. See the entire reference, especially columns 4, 5, 18 21 etc. Note where D in formula (I) of Su et al., is a sulfonyl group ( $\text{SO}_2$ ), K is a direct link X is O and structurally similar species in columns 18, 21, 23, 31. Also note the reference teaches the same utility as currently claimed i.e., activity against Factor  $X_a$ .

#### **Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)**

The difference between the current invention and that of Su et al., reside in the generic description of the compounds. Thus, the skilled artisan would expect the close structural similarities of the compounds to possess similar properties. See *In re Wood*, 199 USPQ 137-142.

Moreover, the motivation as to why one of ordinary skill would conceive and use similar compounds was rendered by the Court which stated in *In re Gyurik et al.*, 596 F.2d 1012, 201 USPQ 552 at 557 that:

“In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness rises from the expectation that compounds similar in structure will have similar properties”. Thus, the instantly claimed method using the compounds would have been suggested to one of ordinary skill in the art.

### **Finding of *prima facie* obviousness---rational and motivation (MPEP §2142-2143)**

Thus, at the time of filing this application one of ordinary skill in the art would have been motivated to prepare compounds as disclosed by the reference, since the reference teaches oxopiperazine compounds and compositions as claimed herein with similar utility. Hence the elected species is allowable; however, the genus is deemed *prima facie* obvious over Su et al., absent a showing to the contrary.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**